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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,866	BROWN, DENNIS M.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☒ Claim(s) *1,6 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

Applicant's amendment and response, and the "In Vivo Cancer Models" reference attached thereto, filed February 10, 2006 has been received and entered into the application.

Accordingly, claims 1, 5-7, 9 and 14 have been amended and claim 15 has been added.

In view of the amendments, the rejection of the claims (i) under 35 U.S.C. § 112, first paragraph, on the grounds that while the specification is enabling for the treatment of an angiogenic disease or inhibiting the progression of an angiogenic disease, such as cancer, an inflammatory disease, (e.g., rheumatoid arthritis, osteoarthritis, asthma and/or pulmonary fibrosis), diabetic retinopathy or macular degeneration, the specification does not reasonably provide enablement for the presently claimed methods which lack a positive recitation of a therapeutic objective to be attained in the claimed hosts and (ii) under 35 U.S.C. § 112, second paragraph, as set forth in the previous Office action dated August 10, 2005 at pages 2-12, are *withdrawn*.

The *Cancer* reference is newly cited by the Examiner, but not relied on, (see the attached form PTO-892), in order to show the general state of the art concerning angiogenesis and leukemia.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 1, 6 and 7 remain objected to because of the following informalities:

In claims 1 and 7, the objectives of "treatment" (claim 1) and "prophylactic" (claim 7) are inconsistent with the function of the amount of the cephalotaxine, i.e., "in an amount *to inhibit...*".

Also, the expression "is administered" in claim 6 does not have antecedent basis in claim 1, where "contacting" is recited. Appropriate correction is required.

In response to this point of objection, Applicant has argued that the Examiner has not provided support for his position and that the requirements in the claims are fully supported by the present specification, (see Applicant's response at the paragraph bridging pages 5 and 6).

The Examiner's objection, however, was not based on the premise that the present specification failed to support, or be consistent with, the claimed terminology identified by the Examiner. Rather, the objection was based on the fact that, with reference to one claimed expression to the other claimed expression, the expressions were not consistent. For example, in claim 1, the stated objective is for treating an angiogenic disease, (claim 1, line 1), while the amount which is administered is not for this purpose, but is an amount sufficient to inhibit angiogenesis. Therefore, the circumstance of treatment which is not inhibitory has not been accounted for in the recitation of the amount of the cephalotaxine which is administered.

In order to overcome the objection, which is based on the lack of formality of the claims, Applicant may wish to consider amending claim 1, line 3 by changing the term "inhibit" to ---treat---. Alternatively, at line 1 of claim 1, the term "treating" could be changed to ---inhibiting---. In both alternatives, the claim language would be consistent. Should Applicant which to further limit the meaning of the term "treating" to mean "inhibiting", such should be

accomplished through proper claim construction, rather than the use of inconsistent claim terminology.

As a similar circumstance appears in claim 7, i.e., the term "prophylactically" at line 1 vs. the term "inhibit" at line 3, the above suggested manner of overcoming the objection may be equally applied to claim 7.

Concerning claim 6, the term "administering" does not find antecedent basis in the claim from which it depends, i.e., claim 1, and therefore remains properly objected to. Again, Applicants' remarks are not germane to this issue because the objection was not directed to an issue of whether or not the term " administering" was supported by the specification. Rather, it was specifically pointed out that the expression "is administered", (claim 6, lines 1-2) does not have antecedent basis in claim 1, where "contacting" is set forth.

In order to overcome this point of objection, Applicant may wish to either (i) amend claim 6 at lines 1-2 by changing "is administered" to ---is contacted to said host---, or (ii) amend claim 1 at line 2 by changing "contacting" to ---administering to---. As another option, claim 6 may be amended at line 1 by inserting, after "wherein", the expression ---said contacting is administering and---. By adopting any one of the above, proper antecedent basis will be present in the claim and this point of objection will be withdrawn.

Claim Rejection - 35 USC § 112, First Paragraph

Claims 7-14 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record as set forth at pages 2-11, as applied to claims 1-14, on the basis that the specification, while being enabling for a method of inhibiting the progression of an angiogenic disease, such as

cancer, an inflammatory disease, (e.g., rheumatoid arthritis, osteoarthritis, asthma and/or pulmonary fibrosis), diabetic retinopathy or macular degeneration, does not reasonably provide enablement for a method of prophylactic treatment or inhibiting the onset, (i.e., interpreted to mean complete inhibiting of such onset, i.e., preventing) the above diseases/disorders, which reasons are here incorporated by reference. As noted above, the points of rejection regarding the lack of a positive recitation of a therapeutic objective to be attained in the claimed hosts is no longer adhered to by the Examiner as this point of rejection has been overcome by Applicant's amendment to claim 1.

Applicant's remarks pertaining the alleged impropriety of the present rejection, which appear at pages 6-7 of the response, have been carefully considered, but fail to persuade the Examiner of error in his determination of non-enablement.

Applicant's position is based on two points, namely, (i) that the Examiner has improperly relied solely on a finding of "previous lack of success" in the cure or prevention of an angiogenic disease as the basis of rejecting the claims, and (ii) the present specification shows the anti-angiogenic effect of the compounds of the invention.

The Examiner is not persuaded by Applicants position because (i) the Examiner has not solely relied on the teachings in the references that it was unknown to be able to prevent or cure the claimed angiogenic diseases to reject the claims, i.e., a "previous lack of success" was not, standing alone, the basis for the Examiner's rejection, and (ii) the data relied on by Applicant shows exactly what Applicant has stated it does, i.e., "The data demonstrates that the application of increasing amounts of a cephalotaxine shows a corresponding decrease in the length of the blood vessels in the CAM, (chicken chorioallantoic membrane)", (response at page 7). Showing

a decrease in the length of the blood vessels, however, does not show that angiogenic disease may be been prevented, (a.k.a., prophylaxed or cured). At the best, it shows that such a disease may be inhibited. The claims, however, are not as limited as the showing and therefor remain properly rejected.

In furtherance of point (i), *supra*, it is clear from the previous Office action that the Examiner has not relied solely on the teachings in the references relied on as a basis for rejecting the claims. The Examiner has also relied on various factors which have been described by the court. Specifically, at page 8 of the previous Office action, the Examiner set forth:

"Also, factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the appropriate factors from those above are applied to the present application (see below) and weighed, it is the Examiner's position that the present specification would only enable the skilled artisan to inhibit the progression of an angiogenic disease.".

Thereafter, the Examiner addressed the pertinent factors, of which the state of the prior art was only one. This consideration is fully consistent with both legal and administrative authority. For example, MPEP § 2107.03 V1, which relates to both the Office's policy and the Court's findings, sets forth:

> "The fact that there is no known cure for a disease, however, cannot serve as the basis for a conclusion that such an invention lacks utility. Rather, Office

> personnel must determine if the asserted utility for the invention is credible based on the information disclosed in the application. Only those claims for which an asserted utility is not credible should be rejected. In such cases, the Office should carefully review what is being claimed by the applicant. An assertion that the claimed invention is useful in treating a symptom of an incurable disease may be considered credible by a person of ordinary skill in the art on the basis of a fairly modest amount of evidence or support. In contrast, an assertion that the claimed invention will be useful in "curing" the disease may require a significantly greater amount of evidentiary support to be considered credible by a person of ordinary skill in the art. *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). See also *Ex parte Ferguson*, 117 USPQ 229 (Bd. Pat. App. & Inter. 1957). "(emphasis added).

Here, as clearly evident from the previous Office action, the Examiner not only considered the teachings in the art, but also the evidence provided in the present specification. Such is fully consistent with the standard of review in situations as this, i.e., "The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of the evidence under consideration", (MPEP § 2107.02 III, citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Accordingly, for the above reasons, the claims are deemed properly rejected.

Suggestion for Overcoming this Rejection

Applicant may wish to considered amending claim 7 by changing, at line 1, the expression "prophylactically treating" to ---inhibiting the onset or progression of--- in order to overcome this rejection. Support for this language may be found throughout the specification as originally filed, e.g., in claim 7, line 3, and thus would not represent new matter.

Claim Rejections - 35 USC § 103

It should be noted that because the Examiner has determined that claims 7-14 are not enabled, these claims have not been further rejected under 35 U.S.C. § 103.

I Claims 1, 4-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. (U.S. Patent No. 3,793,454) in view of D'Amato (U.S. Patent No. 5,712,291) and Kawai et al. (Cancer Letters, 171 (2001) 201-207), each of record, for the reasons of record as set forth in the previous Office action dated August 10, 2005 at pages 12-14, as applied to claims 1 and 4-6, which reasons are here incorporated by reference, in further view of Powell et al., ("Powell II", the newly cited Journal of Pharmaceutical Sciences article which is newly relied on to account for the new requirements represented in amended claim 5 and newly added claim 15).

The amendment to present claim 5 and newly added claim 15 are noted by the Examiner. Such subject matter is not seen to impart patentable moment to the claims because, as shown in the newly cited Powell II article, compounds embraced thereby, i.e., harringtonine, isoharringtonine, homoharringtonine and deoxyharringtonine, (see, e.g., the abstract and page 1229, col. 1), were known in the art as being effective against leukemia, and thus would have been expected to be as useful as the compounds taught in the Powell et al. patent which serves as the primary reference.

Applicant's remarks at pages 8-12 of the response have been carefully considered, but fail to diminish the propriety of the present rejection.

In particular, Applicant has first remarked that Powell fails to teach all limitations of claim 1. This is immaterial here because the rejection is based on obviousness and not on anticipation. Further, Applicant has assigned to Powell a treatment protocol that is not either

expressly or implicitly disclosed. That is, Applicant points out that harringtonine or isoharringtonine were administered to the mice via intraperitoneal injection, (page 9 of the response) and from this reaches the conclusion that "As such, both the tumor cells and the compound are located in the intraperitoneal cavity of the test animals". The Examiner notes that Applicant contemplates the same route of administration, (see claim 6), and thus would be consistent with the teaching of Powell. Applicant then offers that angiogenesis is not associated with tumor cells in such an environment. Insofar as Applicant's method also includes intraperitoneal administration, it also must be that in the present method, such is also the case, i.e., angiogenesis is not associated with tumor cells in this environment. With respect to the D'Amato reference, Applicant offers that this reference is directed to thalidomide compounds and thus fails to teach the "cephalotaxine" requirement of the present claim. This is immaterial because the Examiner has not relied on this reference to show the cephalotaxine aspect of the presently claimed subject matter. With respect to Kawai, Applicant also notes that cephalotaxines are not taught therein. Again, this is immaterial because it was never the Examiner's position that this reference provided such a teaching.

In the above remarks by Applicant, (bridging pages 9-10, Applicant has elected to criticize each reference in isolation and out of the context relied on by the Examiner. Such fails to persuade the Examiner of error in his conclusion of obviousness because it has been well settled that one cannot show non-obviousness by attacking references individually where the rejection is based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the next section at pages 10-11 of their response, i.e., "2. There is no motivation or suggestion to modify the references to make the presently claimed invention", Applicant has apparently constructed his own ground of rejection and then explains why such a ground fails to render obvious the claimed subject matter. Insofar as Applicant's premise of rejection is not the Examiner's, Applicant's remarks to the contrary of the propriety of such a rejection is not germane.

In particular, Applicant disagrees with the Examiner's statement that the skilled artisan would have appreciated the leukemia of Powell et al. to be a non-solid tumor and also be considered an angiogenic disease. In support of this disagreement, Applicant offers a protocol from "In Vivo Cancer Models" to establish that the leukemic cells of Powell et al. would have been in the intraperitoneal cavity of the animals and thus would not have been blood born- or bone marrow-associated leukemia. This does not persuade the Examiner of error because (i) it assumes that Powell et al. are using a protocol that was not in existence at the time of their invention, i.e., Powell et al. has a filing date of April 9, 1970 while in the In Vivo Cancer Model reference, the earliest reference is to a date in 1975, i.e., see the second paragraph in the preface, "The reasons for the selection of these models were presented...on November 10-11, 1975.".

Also, even if this reference was available subsequent to the date of Powell et al., there is nothing in Powell et al. to indicate that any specific protocol was followed. Such an idea can only be found in the writings of Applicant in response to the Examiner's rejection. Further, there is no requirement in the present claims that angiogenesis be present, (i.e., by the construct of present claim 1, "an angiogenic disease" is descriptive of the disease itself and not of the presence or absence of angiogenesis as is true in the expression "an amount sufficient to inhibit

angiogenesis", which is descriptive of a particular amount rather than the presence or absence of angiogenesis), or that the leukemia cells be blood- or bone marrow-associated. Further still, even if such were in the claims, it would be the Examiner's position that from Powell et al., the treatment of leukemias of other types than those specifically taught in the patent would have been obvious given that the animal model of Powell would have been appreciated as being reasonably predictive of results in other hosts, e.g., see the In Vivo Cancer Model reference, the Preface page, the third paragraph thereof, which is here incorporated by reference.

Additionally in this section of Applicant's remarks, it is repeated that with respect to the D'Amato reference, this reference is directed to thalidomide compounds and thus fails to teach the "cephalotaxine" requirement of the present claim. This remains as immaterial as above because the Examiner has not relied on this reference to show the cephalotaxine aspect of the presently claimed subject matter.

At page 12 of the remarks, i.e., under the heading "There is no reasonable expectation of success", Applicants have concluded that "there is no reasonable expectation that modifying the method of Powell to inhibit angiogenesis would succeed.". Such is inconsequential because (i) the claims are not directed to inhibiting angiogenesis, (Applicant should note that such a new concept will not be entertained after this final rejection), and (ii) given the reasoning put forth by the Examiner in the previous Office action, the Examiner is of the opinion that Powell et al. serves as a basis for concluding that it would have been obvious to do what Applicant is doing. The majority of the reasons for relying on the secondary references is for the purpose of interpretation of the disclosed subject matter in order to reconcile such with the subject matter that has been claimed, i.e., to interpret the disclosure of "leukemia" as "an angiogenic disease" or

as "a non-solid tumor", as required by the present claims, additional references, i.e., D'Amato and Kawai, have been relied on.

Nothing in Applicant's remarks has diminished the propriety of the Examiner's interpretation of the claimed subject matter or the teachings of the references relied on in order to reach the conclusion that the claimed subject matter would have been obvious. As such, it is maintained that the present rejection is proper.

Accordingly, for the above reasons, the claims are deemed properly rejected.

II Claims 1-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinery et al. (U.S. Patent Application Publication No. 2001/0049349) in view of D'Amato (U.S. Patent No. 5,712,291), Cecil's Textbook of Medicine (pp. 1060-1074; previously cited by the Examiner), O'Dwyer et al., (Journal of Clinical Oncology article, previously cited by the Examiner) and Medford (U.S. Patent No. 5,380,747), each of record, for the reasons of record as set forth in the previous Office action dated August 10, 2005 at pages 14-19, as applied to claims 1-6, which reasons are here incorporated by reference, in further view of Powell et al., ("Powell II", the newly cited Journal of Pharmaceutical Sciences article which is newly relied on to account for the new requirements represented in amended claim 5 and newly added claim 15).

The amendment to present claim 5 and newly added claim 15 are noted by the Examiner. Such subject matter is not seen to impart patentable moment to the claims because, as shown in the newly cited Powell II article, compounds embraced thereby, i.e., harringtonine, isoharringtonine, homoharringtonine and deoxyharringtonine, were known in the art as being effective against leukemia, (a.k.a., anti-neoplastic agents), (see, e.g., the abstract and page 1229, col. 1), and thus would have been expected to be as useful as the compounds taught in the

Chinery et al. reference which teaches to one of ordinary skill in the art that that anti-neoplastic agents, such as homoharringtonine, are useful, (page 12, alphabetically appearing in paragraph [0152]. The anti-neoplastic activity and close structural similarity of the compounds of Powell II to homoharringtonine would have motivated one of ordinary skill in the art to use the compounds of Powell II in the manner provided for by Chinery et al.

Applicant's remarks at pages 12-16 of the response have been carefully considered, but fail to persuade the Examiner of error in his determination.

Initially, Applicant has remarked that "As currently amended, claim 1 recites a 'method of treating an angiogenic disease in a host comprising contacting said host with a cephalotaxine in an amount sufficient to inhibit angiogenesis, wherein said angiogenic disease is not a solid tumor.' As acknowledged by the Examiner, Chinery fails to teach the angiogenesis inhibition requirement of claim 1. See page 16 of the Office action.". In response thereto, it is first noted that claim 1 does not require that angiogenesis be inhibited. That is, by the construct of present claim 1, the term "angiogenic" in the expression "an angiogenic disease" is descriptive of the disease itself and not of the presence or absence of angiogenesis. Also, the term "angiogenesis" in the expression "an amount sufficient to inhibit angiogenesis" is descriptive of a particular amount rather than the presence or absence of angiogenesis. If the claim were to require inhibition of angiogenesis, it would be positively recited in the claim, that angiogenesis is inhibited. However, such here is not the case. Also, page 16 of the previous Office action has been considered, but it is not seen where the Examiner has acknowledged that Chinery fails to teach angiogenesis inhibition as remarked by Applicant. The only appearance of the term "angiogenesis" on page 16 is where the Examiner notes that Chinery et al. fail to teach "(4) *an*

'amount sufficient to inhibit angiogenesis' (present claim 1)", (emphasis added). This statement refers to *an amount* and not, as characterized by Applicant, an action.

At the section which bridges pages 12 and 13, Applicant has once again remarked that D'Amato does not teach the cephalotaxine requirement of the present invention and neither of Cecil's, Medford nor O'Dwyer teach disclose the angiogenesis inhibition requirement of claim 1. In response, it is first noted that claim 1 does not require angiogenesis to be inhibited. Further, D'Amato was not relied on to show the cephalotaxine requirement of the present invention. Thus, Applicant's remarks here are inconsequential.

In the section under the heading "2. There is no motivation or suggestion to modify the references to make the presently claimed invention", appearing at pages 13-15 of Applicant's response, Applicant has, throughout this section, provided quotations from the Examiner's statement of rejection and has followed such quotations with the remarks that the references relied on (i) fail to "teach the angiogenesis inhibition requirement" of the present claims, (i.e., with respect to Chinery, Cecil's and Medford); and (ii) do not provide a suggestion or motivation to modify the teachings of the reference "to contact a 'host with a cephalotaxine' as required by the present claims", (i.e., with respect to D'Amato; see Applicant's response throughout pages 13-15). The Examiner's response here is the same as set forth several times above. In particular, (i) there is no requirement in the present claims that angiogenesis be inhibited; and (ii) D'Amato was not relied on by the Examiner to show that contacting the host with a cephalotaxine was known or would have been obvious. The Examiner further notes with respect to these repeated remarks of Applicant that such do not address the Examiner's specific reasons for relying on the

references of record and as such, do not address, much less refute, the propriety of the present rejection.

At page 15 of the response, lines 7-9, Applicant has offered a fresh position respecting the Examiner's reliance on Chinery et al. In particular, Applicant has offered that "there is no suggestion or motivation to select homoharringtonine from the listing of antineoplastic agents disclosed by the reference at page 12, paragraph [0152] to treat inflammatory diseases as recited for example in claim 2.".

In response to this position, the Examiner invites Applicant's attention to MPEP § 2131.01, under the heading "A Reference That Clearly Names The Claimed Species Anticipates The Claim No Matter How Many Other Species Are Named", where it is set forth:

> "A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication.')."., (emphasis added).

In Chinery et al., homoharringtonine is specifically named and, given the above, it is immaterial how many other compounds are named. Each and everyone of the anti-neoplastic agents named by Chinery et al. would have been known to one of ordinary skill in the art as being acceptable for use in the invention of Chinery et al. because Chinery et al. clearly advise

the artisan that this is the case. Accordingly, Applicant's position cannot be afforded the significance urged.

At pages 15-16 under the heading "3. There is no reasonable expectation of success", Applicant has once again remarked that none of the references, i.e., Chinery, O'Dwyer, Cecil's and Medford, disclose the angiogenesis inhibition requirement and that D'Amato does not disclose contacting the host with a cephalotaxine. In response thereto, the Examiner's position is again (i) there is no requirement in the present claims that angiogenesis be inhibited; and (ii) D'Amato was not relied on by the Examiner for the proposition that the contacting of a host with a cephalotaxine was known or would have been obvious.

Accordingly, for the above reasons, the claims are deemed properly rejected.

Double Patenting

Provisional Obviousness-Type

I Claims 1-6 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-17 of copending Application No. 10/617,927 for the reasons of record as set forth in the previous Office action dated August 10, 2005 at pages 19-21, as applied to claims 1-6, which reasons are here incorporated by reference. Newly amended claim 5 and newly added claim 15, encompass the homoharringtonine of the co-pending claims, and thus remain/are properly, provisionally rejected.

At page 16 of the response, Applicant has noted that claims 15-17 were subject to a restriction requirement in the '927 application and stand withdrawn. Applicant has not, however, offered any explanation as to why such affects the propriety of the present, provisional rejection.

The fact that the claims are withdrawn does not render the present rejection improper, however, because claims 15-17 of the co-pending application nevertheless remain pending. Until those claims are finally disposed of in that application, they remain as a proper basis for the present, provisional rejection. Accordingly, claims 1-6 and 15 are properly provisionally rejected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

II Claims 1-6 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over either of (i) claims 1 and 16-21 of co-pending Application No. 10/769,638, or (ii) claims 15-20 of co-pending application Serial No. 10/631,106 for the reasons of record as set forth in the previous Office action dated August 10, 2005 at pages 21-22, as applied to claims 1-6, which reasons are here incorporated by reference. Newly amended claim 5 and newly added claim 15, encompass the homoharringtonine of the co-pending claims, and thus remain/are properly, provisionally rejected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

At page 16 of the response, Applicant has stated that the present rejection should be held in abeyance until allowable subject matter has been established in this or the other applications.

Insofar as this is not an argument against the propriety of the present rejection and Applicant has failed to present a proper terminal disclaimer(s), the above rejection is deemed to remain proper.

Accordingly, for the above reasons, the claims are deemed properly rejected.

None of the claims are allowed.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

April 30, 2006